Precisemed GmbH.
Owners Manual for ophthalmic instruments

Warning: These instruments are only intended for the use by professional ophthalmic surgeons who are familiar with the use of these instruments.

Application Range: Medical devices are manufactured for medical use only and should be not misused. They are designed for various eye operations. The attending surgeon is responsible for the selection of the medical devices. The doctor or Hospital is responsible for the adequate training of the surgical staff and for sufficient experience in handling of medical devices.

Information on Use

General Information
Please make sure the instrument is suitable for the intended use.

Preparation Before First Use
Before the first use an instrument must be cleaned thoroughly, tested, and sterilized, i.e. it must be subjected to the same reprocessing procedure as an instrument after the operation. Please make sure the instrument has not been damaged in transit or storage.

Instruments may only be reprocessed by personnel who have undergone the relevant training. The recommendations issued by the German Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) concerning "Hygiene Requirements for the Reprocessing of Medical Devices" must be observed. We assume that trained personnel will have knowledge of these recommendations.

Reprocessing of Instruments

According to EN/ISO 17664 the manufacturer of medical devices is obliged to draw attention to at least one method of cleaning by machine. The process of cleaning by machine explained below was validated in a Miele GD 7735CD with the chemical Deconex 28 AlkaOne (Borer, Zugwil/Switzerland) using the radioisotope method.

Of course other detergents and machines can also be used for reprocessing. In such cases ask your chemical supplier or machine manufacturer whether their products are just as effective as the products with which the method was validated.

Reprocessing Instructions

1. Preliminary Cleaning

Manual Preliminary Cleaning
Rinse all the instruments carefully using warm water as soon as the operation has been completed. Remove any stubborn deposits with a cotton swab. Use soft cleaning brushes for cavities. Rinse out cannulas with a water jet (1.8 bar) for 5 sec. Never use metal brushes or scouring powder. Dismantle take-apart instruments. In the case of forceps, clamps and other instruments with a locking mechanism open the lock.

Ultrasonic Cleaning
As an alternative to or in addition to manual cleaning you can soak the instruments in an ultrasonic cleaning bath for 5 minutes. We recommend ultrasonic cleaning systems with a frequency of at least 40 kHz.

Rinsing and Drying
After cleaning, rinse with purified water (Aqua purificata). Allow the water to drain off properly. Dry carefully with soft cloths or sponges.

2. Cleaning by Machine
(cleaning cycle with chemical/thermal disinfection).
Place the instruments in suitable holders in the washing machine in accordance with the operating instructions issued by the washing machine manufacturer (Miele). Connect cannulas up to the special nozzles.

Run the following cleaning cycle:

4 min Pre-wash with cold water
6 min Clean at 70°C, deconex 28 Alka One 0.5% (Borer Zuchwil)
3 min Neutralize with warm water (>40°C).
2 min Rinse with warm water (>40°C)
Dry

Functional Test
Determination of pH with indicator paper for at least one instrument per cycle.
Functional test in accordance with Miele's operating instructions.
Visual examination for cleanliness.
Check the instruments for loose parts, cracks, rust, and function.
In the case of scissors, forceps, and other instruments with joints, lubricate the joints with a suitable oil or grease (available from us).

Packaging
Use suitable packaging for sterilization. (Either use transparent sterile packaging or a suitable sterilization box (observe the instructions for use issued by the manufacturer of the sterilization box).

Sterilization
We recommend that our instruments be sterilized in an autoclave at 134° C. Observe the operating instructions for the autoclave and the DIN 58946 standard. Flash sterilization is not permitted for instruments with a lumen.

Storage
Store the sterilized instruments in a dry, clean, and dust-free environment at moderate temperatures.

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